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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,288	04/08/2002	Claes Wallen	47865.272600	2442

28694 7590 02/04/2005

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/063,288

Applicant(s)

WALLEN ET AL.

Examiner

Leslie R. Deak

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/26/04.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/16/02.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I in the reply filed on 26 November 2004 is acknowledged. The traversal is on the ground(s) that the device recites the same elements as used in the method. This is not found persuasive because the claimed device does not recite a double membrane anywhere in the limitations, and therefore the claimed method must be practiced with a materially different device. Furthermore, applicant cancelled the nonelected claims.

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 17, the phrase "exhibits" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,445,630 to Richmond. Richmond discloses a connector made of any suitable biocompatible plastic that allows for mixing of fluids with an inlet port (top of spike), injection port 176 with a hydrophobic membrane 182 thereon, and a first duct extending therebetween. The device further comprises an outlet port (bottom of device) with a duct between the port and the inlet, and a luer fitting 88 that makes up a second portion of the device, associated with the outlet port (see FIG 6). The outlet port further comprises a valve 170 that prevents fluid flow until it is dislodged by an inserted member to engage fluid flow. The device may further be provided with a cap (not shown) (see column 6, lines 33-37), any surface may comprise a gripping surface, and the device may be attached to a drip chamber (see column 1, lines 20-25). With regard to the resilience of the materials used for the first and second portions of the device, it is considered a matter of obvious design choice to select various materials for the device. It is held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. Furthermore, Richmond discloses that the 2 portions of the connector device may be formed integrally, while applicant discloses two separate pieces. It would have been obvious to one of ordinary skill in the art at the time of invention to separate the integrated connector into interlocking portions, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Art Unit: 3762

The Richmond device further may comprise a luer connector in the shape of a tube at the end of the outlet (see FIG 3) with varying diameters for allow for snug fluid connection to another vessel. With regard to the claim limitations drawn to the retention forces between two fitted pieces of the claimed device, the limitation amounts to a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114.

With regard to applicant's claim limitations drawn to the method of making the device by injection molding, the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, the limitation has not been given patentable weight.

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 5,199,947 Lopez et al
  - i. Branched fluid conduit with fluid-resistant barriers
- b. US 5,232,109 Tirrell et al
  - ii. Double-cannula infusion device
- c. US 5,782,872 Mueller
  - iii. Branched double-cannula fluid connector

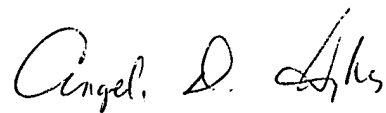
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lrd  
2 February 2005



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SUPERVISORY PATENT EXAMINER  
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